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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,541	06/21/2001	Thomas J. Brennan	R-17	5815

26619 7590 06/23/2004

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San Carlos, CA 94070

EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,541	BRENNAN ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *1-7,9 and 11-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,10 and 17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 3-15-04 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

This application contains claims 1-7, 9 and 11-16 drawn to an invention nonelected with traverse in the reply filed on 11-12-02. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 8, 10 and 17-19 are under consideration in this office action.

Claim Rejections - 35 USC § 101

Claims 8, 10 and 17-19 remain rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility for reasons of record.

Applicants argue the mouse may be used to determine the function of the PAFR gene. Applicants' argument is not persuasive. Studying the mouse to determine the function of the gene is not in and of itself a substantial utility. An invitation to use the mouse for further research to determine the function of the gene is not a substantial utility. The function may be determinable using the mouse. The specification does not

determine the function of the PAFR gene; therefore, the asserted utility is also not credible.

Increased response latency during a hot plate test (increased pain threshold) does not correlate to any disease. Increased time in the central region during an open field test (decreased anxiety) does not correlate to any disease. It cannot be envisioned how to use either phenotype as a model of disease or to test for compounds that alter pain or anxiety in humans using such mice.

Applicants assert a link exists between anxiety in the mice and anxiety or pain found in humans. Applicants assert that such a link is generally accepted in the art of transgenic and knockout mice. Applicants' argument is not persuasive. No link between a disruption in the PAFR gene and pain or anxiety in humans exists. The only way such a link would be "generally accepted in the art of transgenics" would be if scientists determined that some humans with anxiety or pain had a disruption in the PAFR gene. No humans with anxiety or pain have been determined to have a disruption in the PAFR gene.

Applicants argue because the mouse and human gene are homologous, humans having a disruption in the PAFR gene would also have anxiety or increased pain threshold. Applicants' argument is not persuasive. The effect of a disruption in PAFR may affect mice differently than humans. The role of PAFR may be different in mice than humans. The art at the time of filing is replete with examples of proteins that behave differently in mice and humans. Applicants have not linked a PAFR gene disruption to any disease state in humans. Without such teachings, the mouse having a

disruption of a PAFR gene does not have utility because it does not reflect a known human condition.

Applicants argue the mice have uses for models for disease. These arguments are not persuasive because the mice do not reflect any human disease state, i.e. it has not been shown that a disruption in PAFR causes anxiety or increased pain threshold in humans.

Applicants argue the mice can be used to test for drugs that treat anxiety. It cannot be determined how to test drugs for treating anxiety in humans when a disruption PAFR is not the cause of the anxiety. Drugs found using a mouse having a disruption in PAFR may not work if anxiety was caused by environmental factors. Drugs found using mice having a disruption in PAFR may be specific to disruptions in PAFR. However, if the disruption does not occur in humans, then the drugs would not function in humans. If a drug is found using the mouse claimed, and the drug is generic to anxiety caused by any means, then the drug could have been found using any mature wild-type mouse that had anxiety, and the drug would not be specific to a disruption in PAFR.

One of ordinary skill would have been critical of the open field test data in the specification because of the teachings of Crabbe of record. One could not readily conclude from the data in the specification that mice with a disruption had less anxiety. The specification does not teach the control mice were the same strain as the knockout mice. The statistics in Table 1, pg 52, are not significant because comparing two wild-type mice to two knockout mice is not a significant number of samples and because the

data in each group varied widely. One of skill would have seen that the data in Table 1 (pg 52) was not statistically significant and would have realized the results may not have been caused by the disruption of the PAFR gene.

Claim Rejections - 35 USC § 112

Claims 8, 10 and 17-19 also remain rejected under 35 U.S.C. 112, first paragraph for reasons of record. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicants refer to the arguments in the utility rejection, which have been addressed above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 571-272-0804.

The official fax number for this Group is (703) 872-9306.

Michael C. Wilson

MICHAEL WILSON
PRIMARY EXAMINER